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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,426	08/21/2003	Michael Seul	LEAPS-C11	8876

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ERIC P. MIRABEL
35 TECHNOLOGY DRIVE
SUITE 100
WARREN, NJ 07059

EXAMINER	
DO, PENSEE T	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,426	SEUL, MICHAEL	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-79,81-86,88-106 and 108-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-79, 81-86, 88-106, 108-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Parent Data

This application, 10645426, PG Pub. No. 20040037744, filed 08/21/2003 and having 2 RCE-type filings therein; is a continuation of 09690040, filed 10/17/2000 ,now U.S. Patent #6797524. Application 09690040 is a continuation of 09171550, filed 10/26/1998 ,now U.S. Patent #6251691. Application 09171550 is a national stage entry of PCT/US97/08159 , International Filing Date: 04/24/1997 PCT/US97/08159 Claims Priority from Provisional Application 60016642, filed 04/25/1996.

Child Data

Application 11436009, filed on 05/16/2006 is a division of 10645426 , filed on 08/21/2003 and having 2 RCE-type filings therein. Application 11436718, filed on 05/17/2006 is a continuation of 10645426 , filed on 08/21/2003 and having 2 RCE-type filings therein.

Amendment Entry & Claims Status

The amendment filed on February 24, 2009 has been acknowledged and entered.

Claims 76-79, 81-86, 88-106, 108-115 are pending and being examined.

Claimed Invention

76. (Currently Amended) An array comprising several different particle attached ligands, wherein different particle-attached ligands are randomly distributed throughout the

array, wherein different ligands are attached to different particles, and said particles are encoded with a characteristic and that permits identification of the ligand or ligands attached thereto and, permits distinguishing the individual particles including distinguishing different particles from each other, and wherein said particles are in a planar defined area on the surface of a substrate and wherein said particles are affixed to said substrate in a loosely packed, ordered array with the particles in designated positions in accordance with a given outline, such that members of different pairs of adjacent particles are the same distance from one another.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph for claims 104 and 107 in the previous office action is withdrawn herein.

Rejections under 102 and 103 in the previous office action are withdrawn herein because applicants amended the claims to include new limitation "with the particles in a designated positions in accordance with a given outline, such that members of different pairs of adjacent particles are the same distance from one another".

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-79, 81-86, 88-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 76 recites that "the particles are affixed to the substrate in a loosely packed, ordered array". However, the specification fails to provide support for such limitation. The specification on [0009] discloses that "as a function of increasing applied voltage, beads first form planar aggregates in which particles are mobile and loosely packed, then assume a tighter packing, and finally exhibit a spatial arrangement in a form of a crystalline, or ordered array resembling a raft of bubbles". This is interpreted as the beads go through three transformations: 1) mobile and loosely packed; 2) assume tighter packing; 3) spatial arrangement in an ordered array as the applied voltage increases. Therefore, the beads can either be loosely packed, or in an ordered array but never in both stages. However, claim 76 as now recited is interpreted as the beads are loosely packed and at the same time in an ordered array which the specification fails to support.

This is a new matter rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 76, 77, 79, 83, 86, 93, 95, 97, 99, 100, 102, 104, 109, 114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 114, 116, 117, 143, 144 of copending Application No. 11/436,718 in view of Dower (US 5,770, 358).

The instant claims differ from the copending application '718 in that the instant claims are drawn to ligands and copending application '718 recites oligonucleotides. However, in the instant claims, ligands are defined in claims 79 as oligonucleotides. Because the claim sets are drawn to overlapping scope, the claim sets are not patentably distinct. The instant claims also differ in that it recites a "loosely packed, order array" whereas copending applications recite "ordered array". However, it would have been obvious to one of ordinary skills in the art that the particles in copending application '718 are loosely packed because each particle has oligonucleotides

attached to the surface and thus the particles are not touching each other, in other words are loosely packed, because of the oligonucleotides on their surfaces.

The instant claims also differ from the copending application '718 in that they recite that "the members of the different pairs of adjacent particles are the same distance from one another".

Dower teaches arrays comprising encoded particles having analytes wherein the particles are arranged in designated positions in accordance with a given outline (nanofabricated wells, col. 22, lines 41-44), such that members of different pairs of adjacent particles are the same distance from one another (each particle is positioned within an individual well-- col. 22, lines 59-61). Each individual well is the same distance from each other. Thus, each particle in each well is the same distance from one another.

It would have been obvious to one of ordinary skills in the to apply the patterned substrate (nanofabricated wells) and particle arrangement taught by Dower to the substrate of copending application '718 for the added benefit of facilitating manipulation and/or identification of particles and/or particle reactions as taught by Dower (col. 22, line 59-col. 23, line 7).

This is a provisional obviousness-type double patenting rejection.

Claims 76, 77, 79, 83-86, 88, 91-97, 99, 100, 102-104, 106, 108-115 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting

as being unpatentable over claims 114-142 of copending Application No. 11/436,009. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array of particles, and differ in the arrangement of limitations within each set of claims. For example, the instant claims are drawn to ligands where the ligands are defined in claims 79 as oligonucleotides. Because the claim sets are drawn to overlapping scope, the claim sets are not patentably distinct.

Copending application '009 differs from the present claims in that it fails to recite the particles in a loosely packed, ordered array. However, it recites that the particles comprises oligonucleotides on their surfaces and thus the beads are not touching each other or loosely packed because of the oligonucleotides in between the particles. Copending application '009 also recites in claim 122 that the beads are assembled in a predetermined geometry which can include an ordered array.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 76-79, 81-86, 88-106, 108-115 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-46 of copending Application No. 10/310,173 in view of Dower (US 5,770,358).

The copending application '173 fails to claim that "the particles are loosely packed in an ordered array with particles in designated positions in accordance with a

given outline, such that the members of the different pairs of adjacent particles are the same distance from one another".

Dower teaches arrays comprising encoded particles having analytes wherein the particles are arranged in designated positions in accordance with a given outline (nanofabricated wells, col. 22, lines 41-44), such that members of different pairs of adjacent particles are the same distance from one another (each particle is positioned within an individual well-- col. 22, lines 59-61). Each individual well is the same distance from each other. Thus, each particle in each well is the same distance from one another.

It would have been obvious to one of ordinary skills in the to apply the patterned substrate (nanofabricated wells) and particle arrangement taught by Dower to the substrate of copending application '173 for the added benefit of facilitating manipulation and/or identification of particles and/or particle reactions as taught by Dower (col. 22, line 59-col. 23, line 7).

This is a provisional obviousness-type double patenting rejection.

Claims 76-79, 81-86, 88-106, 108-115 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 76-89, 109-115 of copending Application No. 11/436,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets

are drawn to similar arrays and differ only in arrangement of limitations. For example, the instant claims are drawn to ligands where the ligands are defined in claims 79 as oligonucleotides.

Copending application '717 differs from the instant claims in that it fails to recite the particles are loosely packed in an ordered array. Copending '717 recites that the particles are in designated positions in accordance with a given outline having multiple rows of particles.

Thus, it would have been obvious to one of ordinary skills in the art that when the particles in designated positions in accordance with a given outline, they are in an ordered array. Furthermore, they are also loosely packed because they have oligonucleotides in between them and thus are not touching each or are loosely packed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 76-79, 81-86, 88-106, 108-115 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 76-114 of copending Application No. 10/424,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets are drawn to similar arrays and differ only in arrangement of limitations. For example, the instant claims are drawn to ligands where the ligands are defined in claims 79 as oligonucleotides.

Copending application '662 differs from the instant claims in that it fails to recite the particles are loosely packed.

It would have been obvious to one of ordinary skills in the art that the particles in copending '662 are loosely packed because each particle has oligonucleotides attached to its surface and when these particles are arranged in an ordered array, there are always oligonucleotides in between them and thus they are not touching each other or are loosely packed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection

Claims 76-79, 81-86, 88-106, 108-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now recite a newly added limitation requiring **"the particles in a designated positions in accordance with a given outline, such that members of different pairs of adjacent particles are the same distance from one another".** However, Applicants has not pointed to support for the newly added limitation in the present specification.

In paragraph [009] of the pre-granted publication, describes an ordered array resembling a raft of bubble. However, this paragraph does not provide support for the newly claimed "same" distance between the adjacent particles.

Therefore, the specification fails to define or provide disclosure to support this newly added limitation. (see MPEP 2163.06).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76, 77, 79, 83, 86, 89-93, 96, 97, 99-104, 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac (EP 0392546A2 published 17 October 1990) in view of Dower et al. (US 5,770,358, filed September 16, 1992).

Drmanac teaches an array comprising different oligonucleotides attached to different or discrete particles (DNA fragments, col. 7, lines 5-14). The discrete particles are labeled with a unique combination of oligonucleotides so that the particles carrying the DNA can be distinguished and identified (col. 7, lines 4-58, col. 8, lines 1-17). Drmanac also teaches that the particles are mixed and spread in a random monolayer onto a filter in a monolayer of required density followed by fixation (see col. 7, lines 29-33; col. 17, line 29) wherein the particles are anchored to a filter (substrate) (see col. 7, lines 29-30). Drmanac further teaches that the single hybridization area (HA) can be subdivided into "submatrices" (col. 9, line 40 to col. 20, line 1), in which the particles

carry a physical or chemical entity which enables recognition of the particle type (col. 21, lines 9-27). The particles are attached to specific regions of the hybridization area and the exact position of each discrete particle in the HA can be established (see col. 19, line 40-col. 20, line 3). Thus, the particles are in an ordered array or matrix. Regarding "the particles are being fixed in a loosely packed array" or "the particles are not touching each other in an array", since the particle each contains DNA fragments which can be long in length, they must be separated by these DNA fragments and must not touch each other.

For claims 77, Drmanac teaches the particles are fixed to the substrate/filter (see col. 7, lines 29-33).

For claims 79, 83, 90, 99, and 100, Drmanac teaches the ligands are nucleic acids or oligonucleotides of DNA or RNA (see abstract).

For claims 86, 93, 104, 114, Drmanac teaches that the hybridizing probe is attached to a fluorescent molecule (see col. 18, lines 17-22; col. 7, line 45-col. 8, line 17).

For claim 89, Drmanac teaches adding a liquid sample containing analytes to the particles. (see col. 7, lines 17-21).

For claims 91, 111, Drmanac teaches that the single hybridization area (HA) can be subdivided into "submatrices" (col. 9, line 40 to col. 20, line 1).

For claims 92, 112, Drmanac teaches that the location of each array on said substrate in combination with the chemical or physical characteristic indicates the types of ligands therein. (see col. 19, line 40-col. 20, line 3).

For claims 96 and 110, since these particles are in a matrix or an ordered array, the distance between these particles are the same.

For claims 101-103, 113-115, Drmanac teaches attaching oligonucleotide to the particles. (see col. 7, lines 10-13). Since binary encoding requires just the attachment of oligonucleotides to the particles, Drmanac satisfies such requirement.

However, Drmanac fails to teach the array with particles in designated positions in accordance with a given outline, such that members of different pairs of adjacent particles are the same distance from one another.

Dower teaches arrays comprising encoded particles having analytes wherein the particles are arranged in designated positions in accordance with a given outline (nanofabricated wells, col. 22, lines 41-44), such that members of different pairs of adjacent particles are the same distance from one another (each particle is positioned within an individual well-- col. 22, lines 59-61). Each individual well is the same distance from each other. Thus, each particle in each well is the same distance from one another.

It would have been obvious to one of ordinary skills in the to apply the patterned substrate (nanofabricated wells) and particle arrangement taught by Dower to the substrate of Drmanac. Drmanac clearly suggests specific positioning of the particles by specifically teaching matrix and submatrices of hybridization areas. Thus, one of ordinary skills in the art would have been motivated to provide the nanofabricated substrate of Dower for positioning the particles of Drmanac. There would be a reasonable expectation of success and for the added benefit of facilitating manipulation

and/or identification of particles and/or particle reactions as taught by Dower (col. 22, line 59-col. 23, line 7).

Claims 76-79, 81-84, 86, 88-106, 108-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer et al. (5,573,909) and further in view of Dower (US 5,770,358- filed 16 September 1992).

Margel teaches a composition comprising: a) a substrate such as silicon wafer (silicon substrate of claims 84, semiconductor), glass (col. 4, lines 25-31, lines 60-61) in a planar array; b) a population of particles randomly distributed on said sites or wells, said population comprises a plurality of different types of particles with chemical or biochemical binding sites/ligands. (see col. 2, line 35-col. 3, line 5; col. 4, lines 25-65). Regarding claim 88, Margel teaches that immobilization is by chemical bonding or physical bonding. (see col. 3, lines 35-36). The ligands are protein/antibody and biological cells. (see col. 1, lines 40-45; col. 3, lines 23-27). Regarding claim 82, since Margel teaches the use of antibody specific for T-lymphocytes, it is inherent that Margel teaches using monoclonal antibodies because monoclonal antibodies are specific for a cell type. Margel teaches that 1,300 picomoles per squared centimeter protein were bonded to each of the supported microsphere system (see col. 11, lines 7-9). For claim 95, Margel teaches that the average size of the microspheres range from 300 Angstrom to 8 microns which covers the range of 1 micron to 2 microns for claim 95.

However, Margel fails to teach each type of particle comprises a distinct chemical or biochemical binding site and comprises a unique chemical label; the biochemical binding site comprises a nucleic acid and particles are exposed to a sample containing target analyte. Margel also fails to teach the chemical tag is an oligonucleotide.

Singer teaches microparticles having detectably distinct spectral characteristics of a plurality of dyes incorporated into the microparticles that provide a large and effective Stokes shift, wherein in one example a microparticle-labeled probe emits green fluorescence and another microparticle-labeled probe emits red fluorescence, wherein each microparticle with a distinct spectral characteristic is labeled with a different target complement (biochemical binding sites) to bind with different targets in a sample (claim 89). (see col. 1, lines 32-34, col. 4, lines 37-67, col. 13, lines 53-56; col. 16, lines 54-65). Singer also teaches that the microspheres are polyacrolein or polystyrene and that the target and target complement are antibodies and proteins, respectively. (see col. 13, lines 60-63, col. 16, lines 3 and 31). Singer also teaches that a nucleic acid probe on the microparticles is selective for target nucleic acids. (see col. 14, lines 15-62, col. 16, lines 9-12, and 40-43; col. 18, lines 49-51). For claim 93, Singer teaches that the microparticles are fluorescent and comprises an oligonucleotide. (see col. 26, lines 44-46). For claims 101-104, 113-115, since Singer teaches attaching oligonucleotides to microparticles, and the claims define binary encoding is to attach oligonucleotide to particles, Singer satisfies the requirement of binary encoding.

It would have been obvious to one of ordinary skills in the art to modify the composition of Margel with microparticles having distinct spectral characteristics of a

plurality of dyes incorporated into the microparticles and each microparticle is labeled with a different target complement for detecting different target materials in a sample, and such target complement is a nucleic acid as taught by Singer, in order to detect one or more variety of target materials including nucleic acids simultaneously and with high sensitivity since both references teach polyacrolein and polystyrene particles that can immobilize antibodies.

However, Singer and Margel fail to teach the particles are in a loosely packed, order array with the particles in designated positions in accordance with a given outline, such that members of different pairs of adjacent particles are in the same distance from one another or an article of manufacture composition comprising two or more of any of the array defined in claims 76 to 90; and the location of the array on said substrate in combination with the chemical or physical characteristic indicates the types of ligands therein.

Dower teaches arrays comprising encoded particles having analytes wherein the particles are arranged in designated positions in accordance with a given outline (nanofabricated wells, col. 22, lines 41-44), such that members of different pairs of adjacent particles are the same distance from one another (each particle is positioned within an individual well-- col. 22, lines 59-61). Each individual well is the same distance from each other. Thus, each particle in each well is the same distance from one another.

It would have been obvious to one of ordinary skills in the to apply the patterned substrate (nanofabricated wells) and particle arrangement taught by Dower for the

particles of the Margel combined with Singer to accommodate assays of different types of ligands and different samples for multiple screening. There would be a reasonable expectation of success and for the added benefit of facilitating manipulation and/or identification of particles and/or particle reactions as taught by Dower (col. 22, line 59-col. 23, line 7). Regarding an article of manufacture comprising two or more of the arrays in claims 76-90, it would have been obvious to one of ordinary skills in the art to manufacture multiple arrays since the general conditions or method of making the array is taught by Margel, Singer and Dower for the purpose of multiple screenings. Regarding the location and the characteristic of the particle on the substrate of the array indicates the type of the ligands, since the array of Dower is a well plate and each well contains one particle, it would have been obvious to one of ordinary skills in the art to use the location in combination with the characteristic of the particles to indicate the ligands based on the desire to separate beads for individual assays or assay analysis as known in the art.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margel in view of Singer and further in view of Dower as applied to claim 76 above, and further in view of Nacamulli et al. (US 5,527,710).

Margel, Singer and Dower have been discussed above.

However, Margel, Singer and Dower fail to teach that the substrate is an electrode.

Nacamulli teaches antigen coated magnetic particles (particle-attached ligands) are deposited uniformly onto the working electrode from a flow stream by placing the magnet directly below. Electrochemiluminescent labeled antibodies are added and the labeled antibodies to the antigens on the magnetic bead immobilized on the surface of the electrode. (see col. 3, lines 10-30).

It would have been obvious to one of ordinary skills in the art to use the electrode taught by Nacamulli as a substrate for use in the composition taught by Margel and Singer modified by Dower since Margel teaches that the population of particles can be immobilized on semiconductor substrate and Singer teaches that the particles are encoded with labels such as fluorescent labels which can be electrochemiluminescent labels and Nacmulli teaches that detection ECL labels requires as substrate such as an electrode because electrical pulses are needed to apply in order to modulate the ECL output. The ECL signals are useful in monitoring the rates of binding between the proteins/reactants as well as detecting a low concentration of sample.

Declaration

The declaration submitted by Dr. Messing has been reviewed and closely considered. The declaration was submitted to overcome the previous rejection under 112, 1st paragraph, new matter. Most of the declaration discusses enablement issues which was not a component of the previous rejection.

In the declaration, part E, (Packing of particles) pg. 4-5, Dr. Messing submitted that "the examiner rejects the interpretation of the specification that the beads undergo three transformations: 1)mobile and loosely- packed, 2), assume a tighter packing, 3)

spatial arrangement in an ordered array as the applied voltage increases" as new matter.

This is not what constitutes the 112, 1st paragraph rejection in the previous office action. Dr. Messing seems to misunderstand the rejection.

The rejection is thought to be very clear that the specification fails to support for a loosely packed and at the same time ordered array as cited in claim 76 because the specification teaches that the beads undergo three transformations: 1/ loosely-packed, 2/. tighter pack, 3/ ordered array resembling a raft of bubbles. Thus, when the claim recites " loosely-packed, ordered array", it is interpreted that the particles are loosely packed and at the same time in an ordered array while the specification defines that the particles can be in one form at a time, loosely packed or ordered array.

The declaration of Dr. Messing also seems to be relied upon to provide support for the specification's teaching of the newly added limitation, particle distance. While Dr. Messing cites various passages in the specification wherein particles arrangements are provided and produced, none of the cited passages teach members of different pairs of adjacent particles are separated by the same distance as claimed.

Response to Arguments

Applicant's arguments with respect to claims 76-79, 81-86, 88-106, 108-115 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that Drmanac fails to teach the newly added limitation: an ordered array "with the particles in designated position in accordance with a given

outline, such that members of different pairs of adjacent particles are the same distance from one another".

A new reference, US patent 5,770,358 to Dower is applied to remedy the deficiency.

Regarding the 103 rejection by Margel, Singer in view of Gombinski, Applicants argue that Gombinski has a filing date which is after the effective filing date of the present application.

This is found persuasive and Dower is cited to remedy the deficiency in Margel and Singer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Pensee T. Do/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641